

2 122. The sensor assembly of claim 121, wherein the sensor control unit comprises at least one conductive contact and the transcutaneous electrochemical sensor comprises at least one working electrode and at least one contact pad coupled to the at least one working electrode, the at least one contact pad being disposed on a portion of the electrochemical sensor extending out of the skin, wherein the at least one conductive contact is configured and arranged to contact the at least one contact pads.

3 123. The sensor assembly of claim 121, wherein the sensor control unit is adapted to receive a portion of the transcutaneous electrochemical sensor extending out of the skin, the transcutaneous electrochemical sensor comprising a planar substrate.

all cont. 4 124. The sensor assembly of claim 121, wherein the sensor control unit is adapted for placement on the skin over an insertion site of the transcutaneous electrochemical sensor.

5 125. The sensor assembly of claim 121, wherein the sensor control unit is water resistant.

6 126. The sensor assembly of claim 121, wherein the sensor control unit further comprises a battery.

7 127. The sensor assembly of claim 121, wherein the sensor control unit further comprises an alarm to indicate at least one of hypoglycemia, impending hypoglycemia, hyperglycemia, and impending hyperglycemia.

8 128. The sensor assembly of claim 121, wherein the sensor control unit further comprises a rf receiver.

9 129. The sensor assembly of claim 121, wherein the sensor control unit further comprises a processing circuit for determining a level of the analyte from a signal generated by the transcutaneous electrochemical sensor.

10 ~~130~~ 130. The sensor assembly of claim ~~121~~, wherein the analyte is glucose and the non-leachable, analyte-responsive enzyme is a non-leachable, glucose-responsive enzyme.

11 ~~131~~ 131. An analyte monitoring system to monitor a level of an analyte, the analyte monitoring system, comprising:

a transcutaneous electrochemical sensor comprising non-leachable, analyte-responsive enzyme;

a sensor control unit adapted for placement on skin and adapted for receiving a portion of the transcutaneous electrochemical sensor, the sensor control unit comprising a rf transmitter that is configured and arranged to intermittently and repeatedly transmit data related to analyte-dependent signals generated by the electrochemical sensor; and

a display unit comprising a rf receiver to receive the data from the sensor control unit and a display coupled to the rf receiver for displaying an indication of a level of the analyte.

12 ~~132~~ 132. The analyte monitoring system of claim ~~131~~, wherein the display unit further comprises a rf transmitter.

13 ~~133~~ 133. The analyte monitoring system of claim ~~132~~, wherein the sensor control unit further comprises a rf receiver disposed in the housing.

14 ~~134~~ 134. The analyte monitoring system of claim ~~131~~, wherein the display unit further comprises an input device coupled to the display.

15 ~~135~~ 135. The analyte monitoring system of claim ~~131~~, further comprising a calibrator for providing a calibration value to at least one of the display unit and the sensor control unit.

16 ~~136~~ 136. The analyte monitoring system of claim ~~135~~, wherein the calibrator comprises a part of the display unit.

17 ~~137~~ 137. The analyte monitoring system of claim ~~131~~, wherein the display unit is portable.

18 138. The analyte monitoring system of claim 131, further comprising a secondary display unit having a power cord for connecting to an electrical outlet, a receiver for receiving data transmitted by the transmitter, and a display coupled to the receiver for displaying the level of the analyte.

19 139. The analyte monitoring system of claim 131, wherein the display unit further comprises at least one of a lamp, a radio, a clock, an interface to a computer, or a battery backup system.

20 140. The analyte monitoring system of claim 131, wherein the display unit further comprises a pager receiver or an interface to a telephone system to receive messages.

21 141. The analyte monitoring system of claim 131, wherein the display unit comprises a pager transmitter or an interface to a telephone system to send messages.

22 142. The analyte monitoring system of claim 141, wherein the pager transmitter or the interface to the telephone system is activated when at least one of hypoglycemia, impending hypoglycemia, hyperglycemia, or impending hyperglycemia is indicated.

23 143. The analyte monitoring system of claim 131, further comprising a processing circuit in the display unit, the processing circuit being configured to analyze patient-specific data from multiple episodes to predict a patient's response to future episodes.

24 144. The analyte monitoring system of claim 131, wherein the analyte monitoring system further comprises a drug administration system which dispenses a drug based on a level of the analyte.

25 145. The analyte monitoring system of claim 131, wherein the analyte is glucose and the non-leachable, analyte-responsive enzyme is a non-leachable, glucose-responsive enzyme.

26 ~~146~~. A glucose monitoring system, comprising:

a transcutaneous electrochemical glucose sensor;

a sensor control unit adapted for placement on skin and adapted for receiving a portion of the transcutaneous electrochemical glucose sensor, the sensor control unit comprising a rf transmitter that is configured and arranged to intermittently and repeatedly transmit data related to glucose-dependent signals generated by the electrochemical glucose sensor; and

a display unit comprising a rf receiver to receive the data transmitted by the transmitter and a display to display an indication of glucose concentration, wherein the display unit is configured and arranged to determine an insulin administration protocol based on the data.

alt. cont. 27 ~~147~~. The glucose monitoring system of claim 146, further comprising a processing circuit in the display unit, the processing circuit being configured to analyze patient-specific data from multiple episodes to predict a patient's response to future episodes.

28 ~~148~~. The glucose monitoring system of claim 147, wherein the patient-specific data comprises a response to a treatment.

29 ~~149~~. The glucose monitoring system of claim 148, wherein the treatment is an administration of insulin.

30 ~~150~~. The glucose monitoring system of claim 147, wherein the display unit further comprises an input device for indicating when a treatment is administered.

31 ~~151~~. The glucose monitoring system of claim 147, wherein the processing circuit is configured to determine a drug administration protocol in response to the patient-specific data.

32 ~~152~~. The glucose monitoring system of claim 147, wherein the patient-specific data is a dosage dependence of a response to a drug.

33 ~~153~~. The glucose monitoring system of claim 147, wherein the display unit further comprises an input device for indicating when food has been ingested.

34 154. The glucose monitoring system of claim 153, where the input device is configured for indicating an approximate caloric content of the food.

35 155. The glucose monitoring system of claim 146, further comprising a temperature measurement device to correct data obtained from the sensor.

36 156. The glucose monitoring system of claim 146, wherein the glucose monitoring system further comprises a drug administration system which dispenses a drug based on a level of glucose.

37 157. The glucose monitoring system of claim 156, wherein the drug administration system comprises a receiver for receiving data from at least one of the sensor control unit or display unit to direct dispensing of the drug.

38 158. The glucose monitoring system of claim 156, wherein the drug administration system comprises at least one of a needle, syringe, pump, catheter, inhaler, or transdermal patch to administer the drug.

39 159. A glucose monitoring system, comprising:
a transcutaneous electrochemical glucose sensor;
a sensor control unit adapted for placement on skin and adapted for receiving a portion of the transcutaneous electrochemical glucose sensor, the sensor control unit comprising a rf transmitter that is configured and arranged to intermittently and repeatedly transmit data related to glucose-dependent signals generated by the electrochemical glucose sensor; and
a display unit comprising a rf receiver to receive the data transmitted by the transmitter and a display to display an indication of glucose concentration, wherein the display unit is configured and arranged to analyze a plurality of glucose-dependent signals related to a particular type of episode to predict a patient's response to future episodes of the type.

40³⁹ 160. The glucose monitoring system of claim 159, wherein the episode comprises a response to a treatment.

41⁴⁰ 161. The glucose monitoring system of claim 160, wherein the treatment is an administration of insulin.

42⁴⁰ 162. The glucose monitoring system of claim 160, wherein the display unit further comprises an input device for indicating when a treatment is administered.

43³⁹ 163. The glucose monitoring system of claim 159, wherein the display unit is configured to determine a drug administration protocol in response to the episode.

a/c cont. 44³⁹ 164. The glucose monitoring system of claim 159, wherein the episode is a dosage dependence of a response to a drug.

45³⁹ 165. The glucose monitoring system of claim 159, wherein the display unit further comprises an input device for indicating when food has been ingested.

46⁴⁵ 166. The glucose monitoring system of claim 165, where the input device is configured for indicating an approximate caloric content of the food.

47⁴⁵ 167. A method of monitoring glucose, the method comprising:
determining a glucose concentration of a patient using a glucose sensor;
collecting data including the glucose concentration in a personal display unit comprising a transmitter and a receiver;
transmitting the data to a health professional;
transmitting a message, in response to the data, from the health professional to the personal display unit; and
displaying the message from the health professional on the personal display unit.

48 168. The method of claim 167, further comprising inserting transcutaneously the glucose sensor prior to determining the glucose concentration.

49 169. The method of claim 167, wherein the glucose sensor comprises an electrochemical glucose sensor.

50 170. The method of claim 167, further comprising coupling the glucose sensor to a sensor control unit, wherein the sensor control unit is configured and arranged for disposition on skin of the patient, the sensor control unit comprising a rf transmitter, and

transmitting a rf transmission signal from the sensor control unit to the personal display unit based on at least one signal generated by the glucose sensor.

51 171. The method of claim 170, wherein determining a glucose concentration comprises determining a glucose concentration using the personal display unit.

52 172. The method of claim 167, further comprising activating an alarm in the personal display unit, wherein the alarm is configured for activating under one or more of the following conditions: hypoglycemia, impending hypoglycemia, hyperglycemia, and impending hyperglycemia.

53 173. The method of claim 167, wherein transmitting the data comprises transmitting the data to the health professional at regular intervals.

54 174. The method of claim 167, wherein transmitting the data comprises transmitting the data to the health professional when a specific condition is present, wherein the specific condition is one or more of the following: hypoglycemia, impending hypoglycemia, hyperglycemia, and impending hyperglycemia.

55 175. The method of claim 167, wherein transmitting the data comprises transmitting the data using a pager or an interface to a telephone system.

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A sensor assembly to monitor an analyte, the sensor assembly comprising:
a transcutaneous electrochemical sensor; and

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cont.

a sensor control unit adapted for placement on skin, the sensor control unit comprising a power source and a rf transmitter that is configured and arranged to intermittently and repeatedly transmit data related to analyte-dependent signals generated by the electrochemical sensor, wherein the sensor control unit is configured and arranged to both deliver power to the transcutaneous electrochemical sensor and receive the analyte-dependent signals from the transcutaneous electrochemical sensor by inductive coupling between the sensor control unit and the transcutaneous electrochemical sensor.

Remarks

Claim 1 has been canceled and claims 121 to 176 have been added. Accordingly, claims 121 to 176 are presently pending. Support for the claims can be found in the specification as filed. The Examiner is invited to contact Applicant's representative if it is believed that the prosecution of this application may be assisted thereby.

Respectfully submitted,

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